

DOI: 10.31073/onehealthjournal2025-III-05

UDC 343.986:179.1

LEGAL ASPECTS AND ETHICAL STANDARDS OF USING ANIMALS IN SCIENTIFIC RESEARCH

Horiuk Yu.V. (ORCID: 0000-0002-7162-8992)

Higher educational institution «Podillia State University», Kamianets-Podilskyi, Ukraine, email: goruky@ukr.net

Abstract. *The use of animals in scientific research, particularly in biomedical, pharmacological, and veterinary fields, is an important component of scientific progress. However, numerous ethical issues arise regarding their welfare and humane treatment. The aim of this study is to analyze the ethical and legal aspects of using animals in scientific experiments, especially in biomedical and veterinary fields, as well as to evaluate the regulatory acts. A combined approach was used, including theoretical analysis and research of regulatory acts and scientific publications through PubMed and Google Scholar databases. European legislation actively regulates this issue through documents such as Directive 2010/63/EU of the European Parliament and Council. It defines the principles of humane treatment of animals, including minimizing their use in research, applying alternative methods (Replacement), reducing the number of animals (Reduction), and improving experimental methods (Refinement). Moreover, each scientific project involving the use of animals must undergo ethical review, conducted by a commission consisting of specialists in science, ethics, and veterinary medicine. This ensures a balance between scientific needs and animal rights. In Ukraine, there is also a gradual development of legislation regarding animal rights protection. In particular, the Law of Ukraine «On the Protection of Animals from Cruelty» establishes the basic principles of humane treatment of animals. However, there are significant issues, including the insufficient clarity of some provisions, which may be ambiguously interpreted. Additionally, the requirements for using animals in scientific research remain insufficiently strict, and the control over their enforcement is ineffective. Thus, to achieve higher standards of animal protection in Ukraine, it is necessary to improve the legislation, specify norms, and strengthen control over their compliance. It is important to create a system that ensures humane treatment of animals in all spheres, including scientific research, veterinary medicine, daily life, and cultural institutions. Only through continuous improvement of legal mechanisms can an effective balance between scientific progress and the ethics of using animals in research be achieved.*

Keywords: veterinary medicine, animal experiments, legislative initiatives, animal protection, biomedical research.

The use of experimental animals in biomedical, pharmacological, and veterinary research is a crucial aspect of scientific and technological development (Ashall, 2018; Kiraga, 2023). However, the use of living organisms, particularly vertebrate animals, is accompanied by numerous ethical dilemmas that require a responsible and justified approach. The central figure in these discussions is the veterinarian – a specialist who is not only responsible for the physical health of animals but also plays a role in ensuring the ethical standards of experiments (Moses, 2018). Given the growing societal attention to animal rights, humane treatment, and bioethical principles, the ethical aspect of the veterinarian's work in in vivo research has gained particular importance in the scientific and professional community (Morgan, 2007; Díaz, 2021).

Animal testing is an indispensable part of scientific research aimed at developing new drugs, cosmetics, and other medical innovations (Jhandai, 2024). At the legislative level, using of animals in research within the European Union is regulated by a number of regulations, the main goal of which is to reduce animal suffering and ensure high ethical standards (RSPCA, 2017). In particular, these initiatives aim to minimize the use of animals in scientific research,

allowing their use only when it is impossible to obtain the necessary information through alternative methods. A key role in this process is played by the European Parliament and Council Directive 2010/63/EU, which is the main legal act regulating the use of animals in research (EU, 2010).

The issue of the ethics of using animals for scientific experiments is one of the most acute in veterinary and biomedical sciences (Hernandez, 2018). This issue is particularly relevant in the context of the professional activity of the veterinarian, who is responsible for the ethical and legal assessment of animal welfare. As science and technology advance, in vivo research methods are increasingly used, but societal sensitivity to the potential suffering of animals is also growing (Bassil, 2023). Therefore, the modern veterinarian is not only a clinician but also an important participant in the ethical review process of scientific research.

Historically, attitudes toward animals have changed over the centuries. In ancient Greek philosophy, particularly in Aristotle's views, animals were considered lower beings in the hierarchy of living organisms (Koff, 2023). Later, Christian theology denied the moral status of animals, focusing on human interests. However, in the 18th century, philosopher J. Bentham first raised the issue of animal suffering as an ethical category, noting that «the question is not whether they can talk, but whether they can suffer» (Springer, 2021).

Modern ethical models, including utilitarianism, deontology, and virtue ethics, define the framework for ethical discussions regarding animals (Quain, 2021). The utilitarian approach, represented by Peter Singer, allows the use of animals if the benefits to humanity outweigh the suffering of animals. The deontological approach, on the other hand, emphasizes the intrinsic value of animals, regardless of their usefulness to humans.

The issue of animal testing dates back to ancient times, but the first legislative attempts to regulate this field only appeared in the 19th century. Specifically, in 1876, the United Kingdom passed the Animal Protection Act regarding scientific research. European legislation in this area began to take shape in the mid-20th century, when the first rules for regulating the use of animals in scientific research were adopted (Campbell, 2013).

Since the early 1990s, the issue of international regulation of animal testing has become a global concern. The European Union has actively worked on creating a unified legal framework that would reduce the use of animals in research, enhance their protection, and promote the development of alternative research methods.

The aim of this study is to analyze the ethical and legal aspects of animal use in scientific experiments, particularly in biomedical, pharmacological, and veterinary fields, and to evaluate existing regulations governing this process. Studying the legislative initiatives of the European Union and Ukraine concerning animal protection, as well as exploring the mechanisms for implementing humane treatment principles in the context of scientific research, will help identify existing problems in the legislative sphere and suggest ways to address them.

Materials and Methods. The study employed a combined approach, which included both theoretical analysis and practical research based on available literature and legal regulations governing the use of animals for scientific purposes. The primary sources of data were legislative documents, as well as scientific publications concerning the ethics of using animals in biomedical and veterinary research. The evaluation of publications was conducted using databases such as PubMed and Google Scholar to collect the most relevant and influential articles.

Results. *The assessment of European laws that define animal testing regulations.* European legislation regarding animal testing encompasses a wide range of legal acts aimed at achieving a balance between scientific progress and ethical requirements for animal protection (Ashall, 2018; Kiraga, 2023). The main goal of these regulations is to minimize animal suffering, reduce their use in research as much as possible, and promote the development of alternative research methods. The legal framework established by the EU is

based on principles of ethics, science, and human rights, particularly in terms of humane treatment of animals (Hernandez, 2018).

One of the key acts in European legislation is the Directive of the European Parliament and Council 2010/63/EU of September 22, 2010, concerning the protection of animals used for scientific purposes (EU, 2010). This document outlines the fundamental principles, implementation mechanisms, and control over the use of animals in scientific research, providing insight into how animal testing is regulated in EU member states.

The foundation of legislation regarding animal use in scientific research is the 3R principle (Replacement, Reduction, Refinement). This principle requires the application of three main approaches at each stage of an experiment. First, the principle of Replacement, which stipulates that animals should be replaced with alternative methods whenever possible. Such methods include the use of cell cultures, mathematical models, computer simulations, and others. Second, Reduction, which refers to minimizing the number of animals used in research to the minimum necessary to obtain statistically significant results. Third, Refinement, which involves improving research methods and animal care to reduce their suffering. This includes raising standards of animal housing, reducing pain and stress during experiments (Jhandai, 2024).

According to Directive 2010/63/EU, every scientific project involving the use of animals must be assessed by an ethical committee composed of experts in science, ethics, human rights, and veterinary care. These committees evaluate the scientific justification for using animals, assess potential animal suffering, and ensure compliance with the 3R principles. They have the authority to stop research if ethical standards are violated. Furthermore, all institutions conducting research with animals must obtain the relevant licenses, confirming the researchers' qualifications and that the conditions for animal housing meet legal requirements.

Compliance with the norms of this directive is monitored both at the national level and at the EU level. National regulatory bodies conduct regular inspections of laboratories and research institutions to ensure that animal housing conditions meet established requirements and that procedures do not violate ethical standards. In case of violations, fines or even closure of institutions may be imposed. An important aspect of the Directive is the ban on using animals for testing cosmetics and their ingredients, which resulted from years of advocacy by human rights organizations and gained widespread support in the EU.

The implementation of this directive in the national legislations of EU member states involves adapting national laws to the general requirements of the EU, with the possibility of setting additional requirements for more effective animal protection. However, in practice, some countries face challenges in monitoring and verifying compliance with these norms, which leads to differences in the level of enforcement of the directive's requirements (Springer, 2021; Jhandai, 2024).

The European Union actively supports the development of alternative research methods through funding scientific projects aimed at developing new technologies that can replace animals in research. This includes research in the areas of cell cultures, organoids, mathematical models, and artificial intelligence. The key task is to develop methods that can eliminate the need for animals in testing drugs and cosmetic products.

Thus, European legislation on animal testing is based on the principles of ethics, science, and human rights. The application of the 3R principles, the mandatory involvement of ethical committees, the certification of institutions, and the active support of alternative research methods contribute to achieving a balance between scientific needs and humane treatment of animals, reducing their use in research and ensuring proper protection (Campbell, 2013).

Despite the significant steps the European Union has taken to ensure humane treatment of animals in science, several issues remain unresolved. These include the development of alternative methods, ensuring consistent implementation of the directive across all member

states, and overcoming the technical limitations of existing methods. Therefore, it is essential to continue supporting scientific research aimed at finding effective alternatives to animal testing and strengthening the monitoring and reporting system.

Analysis of Ukrainian Legislation on Animal Protection. Animal rights protection in Ukraine is an important component of the country's legal system, which is becoming increasingly relevant with each passing year in the context of integration into international legal standards and the development of civil society. Ukrainian legislation in this area covers various aspects, from legislative initiatives to specific norms and procedures that regulate humane treatment of animals, their housing, use in scientific research, and veterinary care. However, certain issues remain on the path to effective protection of animals from cruelty that need to be addressed.

The protection of animal rights in Ukraine has a constitutional foundation, although this issue is not reflected in a separate article in the Constitution of Ukraine. However, Article 50 of the Constitution of Ukraine states that everyone has the right to a safe environment for life and health, which includes not only natural resources but also living organisms, including animals. This creates a basis for understanding the importance of animal protection in the context of ecological safety and overall well-being. However, the absence of a separate article directly guaranteeing animal rights is a significant gap in Ukrainian legislation, as it may affect the legal significance of subsequent regulatory acts.

One of the main legislative acts regulating animal protection issues is the Law of Ukraine «On the Protection of Animals from Cruel Treatment», adopted in 2006 (Law of Ukraine «On the Protection of Animals from Cruel Treatment», 2006). This law defines the basic principles of humane treatment of animals, prohibiting cruelty, torture, injury, killing, and the creation of conditions that could lead to animal suffering. It also provides for the establishment of minimum standards for the keeping of animals, which is an important step in ensuring their welfare. However, the law does not contain sufficiently clear norms concerning the use of animals in scientific research or the keeping of wild animals in captivity, which has been criticized by human rights defenders and experts.

The Law of Ukraine «On Veterinary Medicine», adopted in 1992, is an important regulatory act in ensuring animal health (Law of Ukraine «On Veterinary Medicine», 1992). It establishes the basic principles of veterinary care and monitoring animal health, including on farms, in zoos, and other places. However, despite the existence of this law, many aspects of veterinary control remain unregulated, especially regarding the keeping of animals that are not used for economic benefit, such as pets or animals in zoos and circuses.

The Law of Ukraine «On Environmental Protection» includes the protection of living organisms but is general in nature and does not provide specific norms for the protection of animals when it comes to their use in scientific research or humane treatment in cultural institutions such as zoos or circuses (Law of Ukraine «On Environmental Protection», 1991).

One of the main problems of Ukrainian legislation is the lack of clarity in some norms, creating space for different interpretations. For example, the concept of «cruel treatment» in the Law «On the Protection of Animals from Cruel Treatment» is often not specified, allowing for ambiguous application of legal norms. Moreover, the existing norms regarding animal housing, particularly in zoos, circuses, and other specialized institutions, do not meet appropriate standards. This includes issues such as limited space, inadequate medical care, and food shortages for animals.

Another significant issue is the insufficiently strict requirements for the use of animals in scientific research. Many research institutions continue to apply outdated methods that do not meet international standards for minimizing animal suffering. The lack of effective control over compliance with animal protection laws, as well as an imperfect system of responsibility for violations, creates additional difficulties in ensuring adequate protection for animals.

To improve the situation, it is necessary to enhance existing legislation by clearly defining animal rights, implementing requirements for their protection in all areas, including scientific, domestic, and cultural sectors. It is also essential to develop specific regulatory acts for specific categories of animals, such as pets, wild animals in captivity, and animals used in research. Furthermore, monitoring compliance with animal protection requirements should be strengthened, and effective mechanisms for monitoring and accountability should be created.

Thus, animal rights protection in Ukraine requires not only strengthening the legislative framework but also improving control and oversight mechanisms. Systemic reforms in this area aim to ensure more humane treatment of animals and improve the effectiveness of law enforcement, contributing to the adherence to international human rights standards and environmental protection.

Conclusion. The use of animals in scientific research, particularly in biomedical, pharmacological, and veterinary fields, is a vital component of progress in science and technology. However, this raises serious ethical concerns that require a responsible approach to animal welfare. At the European Union level, there are a number of legislative initiatives regulating the use of animals in research, notably Directive 2010/63/EU, which encourages the application of the 3Rs principles (Replacement, Reduction, Refinement) to minimize animal suffering and promote the development of alternative research methods. Increased attention to research ethics, as well as the involvement of ethical committees, are essential elements to ensure humane treatment of animals. From a Ukrainian perspective, the situation also requires attention. The country's legislation is gradually integrating into international standards, but significant gaps remain, notably the lack of clearly defined animal rights at the constitutional level, and insufficiently developed norms regarding their use in scientific research. Legislative acts such as the LU «On the Protection of Animals from Cruel Treatment» and the LU «On Veterinary Medicine» need to be improved to create clearer and more effective control mechanisms. To ensure proper animal protection in Ukraine, it is necessary to enhance the existing legal framework, clarify terms and norms, and improve compliance monitoring. An important step is the development of specific regulatory acts that will address the needs of different categories of animals and ensure their humane treatment in all spheres of public life, particularly in scientific research.

REFERENCES

1. Ashall V., Millar K.M., Hobson-West P. (2018) Informed consent in veterinary medicine: ethical implications for the profession and the animal 'patient'. *Food Ethics*; 1:247-258. doi: 10.1007/s41055-017-0016-2.
2. Bassil K., Horstkötter D. (2023) Ethical implications in making use of human cerebral organoids for investigating stress—related mechanisms and disorders. *Cambridge Quarterly of Healthcare Ethics*. 32(4): 529-541. doi: 10.1017/S0963180123000038.
3. Campbell M.L.H. (2013) The role of veterinarians in equestrian sport: A comparative review of ethical issues surrounding human and equine sports medicine. *Vet J.*;197(3):535-540. doi: 10.1016/j.tvjl.2013.05.021.
4. Díaz L., Zambrano E., Flores M.E., Contreras M., Crispín J.C., Alemán G., Bobadilla N.A. (2021) Ethical considerations in animal research: the principle of 3R's. *Revista de investigacion clinica*. 73(4): 199-209. doi: 10.24875/ric.20000380.
5. Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes. OJ L 276. 2010 Oct 20:33–79. Available from: <https://eur-lex.europa.eu/eli/dir/2010/63/oj>.
6. Hernandez E., Fawcett A., Brouwer E., Rau J., Turner P. (2018) Speaking Up: Veterinary Ethical Responsibilities and Animal Welfare Issues in Everyday Practice. *Animals*; 8(1):15. doi: 10.3390/ani8010015.
7. Jhandai P., Soni D., Rani R. (2024) Surveying veterinarians on ethical dilemmas and moral distress within veterinary practice. *Int J Adv Biochem Res*; 8(3S):174-177. doi: 10.33545/26174693.2024.v8.i3sc.714

8. Kiraga Ł., Dzikowski A. (2023) Ethical Concerns of the Veterinarian in Relation to Experimental Animals and In Vivo Research. *Animals*; 13(15):2476. doi: 10.3390/ani13152476
9. Koff W.C., Rappuoli R., Plotkin S.A. (2023) Historical advances in structural and molecular biology and how they impacted vaccine development. *J Mol Biol.*;168113. doi: 10.1016/j.jmb.2023.168113
10. Morgan C.A., McDonald M. (2007) Ethical Dilemmas in Veterinary Medicine. *Vet Clin North Am Small Anim Pract.*; 37(1):165-179. doi: 10.1016/j.cvsm.2006.09.008
11. Moses L., Malowney M.J., Wesley Boyd J. (2018) Ethical conflict and moral distress in veterinary practice: A survey of North American veterinarians. *J Vet Intern Med.*; 32(6):2115-2122. doi: 10.1111/jvim.15315
12. On Environmental Protection: Law of Ukraine dated June 26, 1991 No. 1264-XII: as of November 15, 2024. Available from: <https://zakon.rada.gov.ua/laws/show/1264-12#Text>.
13. On the Protection of Animals from Cruel Treatment: Law of Ukraine dated February 21, 2006 No. 3447-IV: as of November 15, 2024. Available from: <https://zakon.rada.gov.ua/laws/show/3447-15#Text>.
14. On Veterinary Medicine: Law of Ukraine dated June 25, 1992 No. 2498-XII: as of January 18, 2025. Available from: <https://zakon.rada.gov.ua/laws/show/2498-12#Text>.
15. Quain A., Ward M.P., Mullan S. (2021) Ethical Challenges Posed by Advanced Veterinary Care in Companion Animal Veterinary Practice. *Animals.*; 11(11):3010. doi: 10.3390/ani11113010
16. RSPCA (2017) Guidelines for the use of animals in scientific research. Royal Society for the Prevention of Cruelty to Animals. Available from: <https://www.rspca.org.uk>.
17. Springer S., Sandøe P., Grimm H., Corr S.A., Kristensen A.T., Lund T.B. (2021) Managing conflicting ethical concerns in modern small animal practice—A comparative study of veterinarian's decision ethics in Austria, Denmark and the UK. *PLoS One.*;16(6):e0253420. doi: 10.1371/journal.pone.0253420

ПРАВОВІ АСПЕКТИ ТА ЕТИЧНІ НОРМИ ВИКОРИСТАННЯ ТВАРИН У НАУКОВИХ ДОСЛІДЖЕННЯХ

Горюк Ю.В. (ORCID: 0000-0002-7162-8992)

Заклад вищої освіти «Подільський державний університет», Кам'янець-Подільський, Україна, email: goruky@ukr.net

Резюме. Використання тварин у наукових дослідженнях, зокрема в біомедичних, фармакологічних та ветеринарних галузях, є важливою складовою наукового прогресу, проте виникає безліч етичних питань щодо їхнього добробуту та гуманного ставлення. Метою дослідження є аналіз етичних і правових аспектів використання тварин у наукових експериментах, зокрема в біомедичних та ветеринарних галузях, а також оцінка існуючих нормативних актів. Використано комбінований підхід: теоретичний аналіз і дослідження нормативних актів та наукових публікацій через бази даних PubMed та Google Scholar. Європейське законодавство активно регулює це питання через такі документи, як Директива Європейського парламенту і Ради 2010/63/ЄС. Вона визначає принципи гуманного ставлення до тварин, включаючи мінімізацію їхнього використання в дослідженнях, застосування альтернативних методів (Replacement), зменшення кількості тварин (Reduction) і вдосконалення методів проведення експериментів (Refinement). Крім того, кожен науковий проект, що передбачає використання тварин, має проходити етичну експертизу, яка здійснюється комісією, до складу якої входять спеціалісти з науки, етики та ветеринарії. Це дозволяє забезпечити баланс між науковими потребами та правами тварин. В Україні також спостерігається поступовий розвиток законодавства щодо захисту прав тварин. Зокрема, Закон України «Про захист тварин від жорстокого поводження» визначає основні принципи гуманного ставлення до тварин. Однак існують значні проблеми, зокрема в недостатній чіткості деяких норм, що можуть бути трактовані неоднозначно. Крім того, вимоги до використання тварин у наукових дослідженнях залишаються недостатньо суворими, а контроль за

їхнім дотриманням – неефективним. Таким чином, для досягнення більш високих стандартів захисту тварин в Україні необхідно удосконалити законодавство, конкретизувати норми та посилити контроль за їхнім дотриманням. Важливо створити систему, що забезпечить гуманне ставлення до тварин в усіх сферах, зокрема в наукових дослідженнях, ветеринарії, побуті та культурних установах. Тільки через постійне вдосконалення правових механізмів можна досягти ефективного балансу між науковим прогресом та етикою використання тварин у дослідженнях.

Ключові слова: ветеринарна медицина, експерименти на тваринах, законодавчі ініціативи, захист тварин, біомедичні дослідження.

DOI: 10.31073/onehealthjournal2025-III-05